The Examiner asserts that a unity of invention, as required under Rule 13.2 PCT, is satisfied "where a group of inventions are claimed in one and the same international application, the requirement of unity of invention…shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. Further, "the expression "special technical features" shall mean those technical features that define a contribution, which each of the claimed inventions, considered as a whole, makes over the prior art so linked as to form a general inventive concept. The Examiner states that the "technical feature linking Groups I-III is a stable oral composition of azithromycin."

Tenegauzer *et al.* (US 2003/0176369 A1) is cited as the closet prior art and describes stabilized azithromycin compositions comprising an intimate mixture of azithromycin and a stabilizing-effective amount of an antioxidant to improve the resistance of the azithromycin to degradation. *See* Abstract. Further, "[i]n particular, the amine group of azithromycin is susceptible to oxidation." *See* Page 1, Paragraph [0005]. Tenegauzer states that the "quantities of impurities present before and after oxidative stress were quantified by high performance liquid chromatography." *See* Page 4, Paragraph [0050]. Tenegauzer also discloses that azithromycin ethanolate monohydrate is the starting material for all examples. *See* Page 2, Paragraph [0019] and Examples 1-6.

However, Tenegauzer fails to teach one skilled in the art to formulate a pharmaceutical composition that prevents the conversion of azithromycin monohydrate into other hydrates, namely azithromycin dihydrate. Tenegauzer does not disclose the hydrate purity of the final compositions produced according to any of the disclosed embodiments, nor does it provide any motivation or teachings to one skilled in the art to modify the embodiments in anyway to prevent such conversion. The technical feature of Tenegauzer is to provide for prevention of chemical degradation directly to the azithromycin molecule, and more specifically to the amine group of azithromycin; it does not address or disclose anywhere in the specification how to reduce, prevent, or eliminate any conversion between different azithromycin hydrates.

According to the present invention, Applicants submit that the technical feature linking Groups I, II, and III is the prevention of conversion of azithromycin monohydrate to other hydrates, in particular azithromycin dihydrate. Polymorphic (hydrate) stability, as accomplished herein, is distinct from the conversion of the active molecule into impurities. Therefore, Applicant's technical feature should be correctly deemed as a "special technical feature" as defined under PCT Rule 13.2 because it constitutes a definite contribution over the prior art (Tenegauzer). As such, Group I, II, and III claims maintain a unity of invention as defined under PCT Rule 13.1.

Conclusion

In light of the above remarks, Applicant respectfully requests reconsideration and withdrawal of the restriction requirement.

Authorization is hereby given to charge any fees deemed to be due in connection with this Response to Deposit Account No. 50-0912.

Respectfully submitted,

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